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**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

JUDITH PUSEY and DONALD PUSEY,

Husband and Wife
10 N. Lexington Avenue
Havertown, PA 19083

Plaintiff (s)

v.

BAXTER INTERNATIONAL Inc.

One Baxter Parkway
Deerfield, Il 60015

and

BAXTER HEALTHCARE CORPORATION

One Baxter Parkway
Deerfield, Il 60015

and

BECTON, DICKINSON and COMPANY

1 Becton Drive
Franklin Lakes, New Jersey 07417

Defendants

10 -3344

No.:

FILED

JUL 7 2010

By ^{MIC} _{Dep. Clerk}

COMPLAINT - CIVIL ACTION

1. Plaintiff, Judith Pusey, is an adult individual, citizen and resident of the Commonwealth of Pennsylvania, residing therein at 10 N. Lexington Avenue, Havertown, Pennsylvania, 19083.

2. Plaintiff, Donald Pusey, is an individual, citizen and resident of the Commonwealth of Pennsylvania, residing therein at 10 N. Lexington Avenue, Havertown, Pennsylvania, 19083. At all times material hereto Donald Pusey was the husband of plaintiff, Judith Pusey.

3. Defendant, Baxter International Inc., (hereinafter referred to as "Baxter"), is and was, and at all times material hereto was, a corporation organized and existing under the laws of the State of Delaware, with a principal place of business located in the State of Illinois at One Baxter Parkway, Deerfield, Il. 60015, and which regularly did business in the Commonwealth of

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Pennsylvania.

4. Defendant, Baxter Healthcare Corporation, (hereinafter referred to as “Healthcare”), is and was, and at all times material hereto was, a corporation organized and existing under the laws of the State of Delaware, with a principal place of business located in the State of Illinois at One Baxter Parkway, Deerfield, Il. 60015, and which regularly did business in the Commonwealth of Pennsylvania.

5. Defendant, Becton, Dickinson and Company, (hereinafter referred to as “BD”), is and was, and at all times material hereto was, a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business located therein at 1 Becton Drive, Franklin Lakes, New Jersey, and which regularly did business in the Commonwealth of Pennsylvania.

6. At all times material hereto, defendants, Baxter, Healthcare and BD, were engaged in the business of designing, manufacturing, distributing and selling medical equipment and supplies. The defendants herein regularly placed into the stream of commerce products which were sold in and used in the Eastern District of Pennsylvania, and therefore venue is proper in the United States District Court for the Eastern District of Pennsylvania.

7. At all times material hereto, defendants, Baxter, Healthcare and BD were acting by and through their respective officers, directors, managing agents, employees, servants and/or workmen, who were all acting in the course and scope of their employment with respect to the allegations set forth herein.

8. At all times material hereto, plaintiff, Judith Pusey, was receiving medical treatment from R. Barrett Noone, M.D., 888 Glenbrook Avenue, Bryn Mawr, Pa 19010. Dr.

Noone practices in Montgomery and Philadelphia Counties.

9. On or about February 25, 2008, plaintiff, Judith Pusey, came under the care of Dr. Noone, for the placement of a left breast implant, after her left breast was removed as the result of breast cancer.

10. On or about February 28, 2008, plaintiff, Judith Pusey, underwent a series of visits with Dr. Noone during which he began to expand the left breast, with saline solution, for the placement of a permanent breast implant.

11. On or about July 11, 2008, plaintiff, Judith Pusey, received her last expansion of the breast with saline solution. The saline solution in question was manufactured, sold and distributed by defendants, Baxter and Healthcare. The syringe and needle in question were manufactured, sold and distributed by defendant, BD. Within 48 hours, after inflation of the breast, with defendants' products, the plaintiff became symptomatic, with a cellulitis of her chest, at the site of injection, and with subsequent fever.

12. On or about July 17, 2008, plaintiff, Judith Pusey, once again went to Dr. Noone because her left breast become red and swollen. During that visit Dr. Noone aspirated 50 ccs of straw colored fluid and prescribed antibiotics. The aspirated material was submitted for laboratory evaluation.

13. On or about July 18, 2008, plaintiff, Judith Pusey was once again at Dr. Noone's office, at which time she had a fever.

14. On or about July 20, 2008, plaintiff, Judith Pusey, was admitted to Bryn Mawr Hospital for an exploration and drainage of an abscess in her left breast, and removal of her left breast expander.

15. On or about July 20, 2008, plaintiff's, Judith Pusey's, laboratory studies demonstrated that her left breast was contaminated with Staphylococcus bacteria.

16. As the result of defendants' conduct it was necessary to remove plaintiff's left breast expander and related instruments.

17. As a consequence of the removal of the left breast expander and related instruments, the condition of the breast and skin made breast reconstruction very difficult. As a result, plaintiff will be unable to have the left breast reconstructed.

18. Plaintiff's injuries and infection was caused by defendants' dangerous, defective saline solution, and/or the needle and/or the syringe, which was used by Dr. Noone for the percutaneous inflation of the plaintiff's breast expander.

19. Plaintiff's injuries and damages were caused by the dangerous and defective saline solution, and/or the needle and/or the syringe, which were purchased new, and which reached plaintiff in substantially the same condition as when they left the possession and control of the defendant manufacturers.

20. In late September 2009, Plaintiff's right breast implant, which had previously been placed due to cancer in the right breast, "blew out."

21. On or about October 30, 2009, the implant in plaintiff's right breast had to be removed due to this "blow out."

22. As a consequence of the prior removal of her left breast, with the subsequent removal of the right breast, plaintiff has been left without any breasts.

23. Had it not been for the removal of plaintiff's left breast, as a result of the infection caused by the dangerous and defective saline solution, and/or the needle and/or the syringe,

plaintiff would have had the right breast replaced.

24. As the result of the loss of the left breast, however, and the inability to repair it, plaintiff was not able to repair her right breast, such that plaintiff now lacks both breasts.

25. At all times material hereto, the saline solution, the needle and the syringe, were being used by the plaintiff's physician, Dr. Noone, for the foreseeable intended purposes for which they were designed, manufactured, assembled, supplied and sold, and in a manner which was reasonably foreseeable to defendants.

26. The needle and/or the syringe, manufactured by BD, were defective in that:

- (a) The package seal and package seal integrity (and resulting product sterility) was adversely affected when the product was exposed to low atmospheric pressure during shipment of the product;
- (b) Defendant, BD, failed to protect individuals from the normal aspects of the shipment of the product;
- (c) Defendant, BD, failed to protect individuals from hazards by failing to protect the product from the normal aspects of shipment of the product by air;
- (d) Defendant, BD, failed to warn users of its product of the dangers inherent in the shipment of its product under the conditions it was shipped;
- (e) Defendant, BD, failed to adequately package its product;
- (f) Defendant, BD, failed to take precautions to insure that its packaging and the content of its syringe would not be damaged during shipment;
- (g) The product failed to have any safety warnings on it;
- (h) Foreseeable use of the product required that it be used without any further checks of the product's integrity.

27. The saline solution, manufactured by defendants, Baxter and Healthcare, was defective in that:

- (a) Its package seal and package seal integrity (and resulting product sterility) were defective;
- (b) Defendants, Baxter and Healthcare, failed to protect individuals from the normal aspects of the shipment of their product;
- (c) Defendants, Baxter and Healthcare, failed to protect individuals from hazards by failing to protect the product from the normal aspects of shipment;
- (d) Defendants, Baxter and Healthcare, failed to warn users of their product of the dangers inherent in the shipment of their product under the conditions it was shipped;
- (e) Defendants, Baxter and Healthcare, failed to adequately package their product;
- (f) Defendants, Baxter and Healthcare, failed to take precautions to insure that the packaging of their product would not be damaged during shipment;
- (g) The product's packaging failed to have any safety warnings on it;
- (h) Foreseeable use of the product required that it be used without any further checks of the product's integrity.

28. The Defendants, Baxter, Healthcare and BD, are strictly liable to plaintiff as set forth above, and as follows:

- (a) For selling a product in a defective condition, unreasonably dangerous for its intended use;
- (b) For failure to properly and adequately provide safety warnings on their products;
- (c) For failure to give adequate and complete warnings of the known or knowable dangers involved in the use and exposure to their products;
- (d) For failure to adequately package their product;
- (e) For failure to warn plaintiff and her physician of the dangerous nature of their product;

- (f) For failure to provide adequate instructions for the use of their product;
- (g) For failure to adequately design their product, such that it reached plaintiff in a defective condition;
- (h) For other defects as may become evident through the course of discovery or trial.

29. As a direct and proximate result of the defective nature of the products, plaintiff, Judith Pusey, has suffered, and will continue to suffer, for an indefinite period in the future, severe personal injuries and losses, some or all of which may be permanent, including but not limited to the following:

- (a) Infection in the left breast;
- (b) Loss of her left breast implant;
- (c) Pain;
- (d) Inability to receive a replacement breast implant;
- (e) Sensitivity to temperatures;
- (f) Subsequent surgery to remove the infected breast implant;
- (g) Scarring;
- (h) Extreme Pain and Suffering
- (i) Permanent scarring and disfigurement;
- (j) Inability to restore the left breast;
- (k) Infection;
- (i) Loss of the right breast.

30. As a direct and proximate result of the defective and infectious nature of the saline solution, and/or the needle and syringe, plaintiff, Judith Pusey, has suffered and will continue to

suffer for an indefinite period in the future:

- (a) Pain and suffering;
- (b) Mental anguish, embarrassment and humiliation;
- (c) Loss of well being, loss of life's pleasures, restrictions in the ability to engage in and enjoy normal activities, and other intangible losses;
- (d) Emotional suffering;
- (e) Loss of potential earnings and earning capacity;
- (f) Disfigurement and scarring.

COUNT I- NEGLIGENCE

31. Plaintiffs incorporate by reference the averments in all preceding paragraphs of the Complaint as if set forth at length herein.

32. The aforementioned personal injuries and losses, suffered by the plaintiffs, are the direct and proximate result of the unreasonably dangerous condition of the saline solution, and/or the needle and/or the syringe, and are the result of the negligence, carelessness, and recklessness of the defendants, acting individually or in concert, and of their agents, servants, employees, and apparent agents acting within and during the scope of their employment, authority, or apparent authority, and are not due to any act or failure to act on the part of the plaintiffs, or Mrs. Pusey's physician, R. Barrett Noone, M.D.

33. The unreasonably dangerous condition of the saline solution, and/or the needle and/or the syringe, and the negligence, carelessness, and recklessness of the defendants, were substantial contributing factors in bringing about the plaintiff's injuries and losses.

34. At all times material hereto, the saline solution, and/or the needle and/or the syringe, were being used by plaintiff's physician Dr. Noone, for the foreseeable intended purposes for which they were designed, manufactured, assembled, supplied and sold, and plaintiff was a foreseeable user of the saline solution, and/or the needle and/or the syringe.

35. Defendants, Baxter, Healthcare and BD, knew or should have known of the dangers and hazards posed to intended users, such as plaintiff, Judith Pusey, by the products which they designed, manufactured, distributed, and/or sold and which were ultimately used by plaintiff's doctor, on plaintiff.

36. Nevertheless, despite their knowledge or reason to know of the dangers and hazards posed to intended users, such as Mrs. Pusey, defendants, Baxter, Healthcare and BD, failed to take measures to correct known defects and to reduce the risk of injury through the use of their products on plaintiff, by plaintiff's physician.

37. Defendants, Baxter, Healthcare and BD, knew or should have known of the dangers and hazards posed by their products but failed to take steps to recall their products in a timely manner.

38. The negligence, carelessness, and recklessness of defendants, Baxter, Healthcare and BD, included, but are not limited to the following:

- (a) Failure to provide their product with sufficient and adequate packaging to avoid contamination;
- (b) Failure to change the packaging of the products after defendants knew of the defects in the packaging;
- (c) Failure to properly test, evaluate, inspect, and assemble their packaging and its contents;

- (d) Negligent design and manufacture of their packaging and its contents;
- (e) Failure to warn the public in general and plaintiff in particular about the dangers presented by the use of defendants' product;
- (f) Failure to withdraw its product from the market in a timely manner;
- (g) Supplying plaintiff's physician and plaintiff with a dangerous and defective product;
- (h) Vicarious liability for the negligence of its agents, servants, employees, and apparent agents acting within the course and scope of their employment, agency, or apparent agency;

WHEREFORE, plaintiffs, Judith Pusey and Donald Pusey, husband and wife, hereby demand judgment against defendants, Baxter, Healthcare and BD, in an amount in excess of one hundred thousand dollars (\$100,000.00), exclusive of interest and costs, together with prejudgment interest, post-judgment interest, delay damages, costs and attorneys' fees.

**COUNT II: STRICT LIABILITY IN TORT UNDER
SECTION 402(a) OF THE RESTATEMENT (SECOND) OF TORTS**

39. Plaintiffs incorporate by reference the averments in all preceding paragraphs of the Complaint as though set forth at length herein.

40. Defendants, Baxter, Healthcare and BD, are the manufacturers, designers, distributors, and/or sellers of the saline solution, and/or the needle and/or the syringe, which were used to inject into plaintiff's breast.

41. The saline solution, and/or the needle and/or the syringe were sold and delivered to R. Barrett Noone, M.D. At all times prior to delivery, the saline solution, and/or the needle and/or the syringe were in the exclusive control of defendants, Baxter, Healthcare and BD, their agents, servants, and employees, and were delivered to Dr. Noone without substantial change in

their condition.

42. The saline solution, and/or the needle and/or the syringe were used on the plaintiff, Judith Pusey, by her physician, R. Barrett Noone, M.D., as designed and intended by the defendants, without any change in their condition from the time they left the control of the defendants, and were used on the plaintiff, by Dr. Noone.

43. The saline solution, and/or the needle and/or the syringe which were sold and delivered to Dr. Noone, by defendants, Baxter, Healthcare and BD, their agents, servants, and employees, and ultimately used on the plaintiff, were, at the time of sale and delivery, in a defective condition and unreasonably dangerous to the ultimate users; as such, defendants are strictly liable to plaintiff pursuant to Section 402(a) of the Restatement (Second) of Torts and supporting case law.

44. The saline solution was defective for the following reasons:

- (a) Its package seal allowed for the introduction of bacterial and/or other deleterious substances to be introduced into the product and then the plaintiff;
- (b) It lacked adequate warnings;
- (c) It was shipped in a defective manner;
- (d) Defendants, Baxter and Healthcare, failed to adequately warn of the defective nature of their product in a timely manner.

45. The syringe and needle were defective for the following reasons:

- (a) Either the syringe or needle allowed for the introduction of bacterial and/or other deleterious substances into the product and then into the plaintiff;
- (b) Either the syringe or needle lacked adequate warnings;
- (c) Either the syringe or needle was shipped in a defective manner;

- (d) Defendant, BD, failed to adequately warn of the defective nature of its product in a timely manner.

46. As a direct and proximate result of the defective condition of the saline solution, and/or the needle and/or the syringe plaintiff, Judith Pusey, sustained the injuries and losses described herein.

WHEREFORE, plaintiffs, Judith Pusey and Donald Pusey, husband and wife, hereby demand judgment against defendants, Baxter, Healthcare and BD, in an amount in excess of one hundred thousand dollars (\$100,000.00), exclusive of interest and costs, together with prejudgment interest, post-judgment interest, delay damages.

**COUNT III: BREACH OF EXPRESS AND
IMPLIED WARRANTY OF MERCHANTABILITY**

47. Plaintiffs incorporate by reference the averments in all preceding paragraphs of the Complaint as though set forth at length herein.

48. Defendants, Baxter, Healthcare and BD, are the designers, manufacturers, assemblers, distributors and sellers of the saline solution, and/or the needle and/or the syringe, which was shipped by defendants to plaintiff's physician, R. Barrett Noone, M.D., who in turn used it on, and injured the plaintiff, Judith Pusey.

49. Defendants, Baxter, Healthcare and BD, expressly and impliedly warranted that their products were merchantable, fit and safe for the ordinary purpose for which they were sold and used.

50. Defendants, Baxter, Healthcare and BD, breached these express and implied warranties by designing, manufacturing, distributing, and selling their products in a defective, harmful, and unmerchantable condition.

51. As a direct and proximate result of said breach of express and implied warranties, plaintiff, Judith Pusey, sustained the injuries and losses described herein.

WHEREFORE, plaintiffs, Judith Pusey and Donald Pusey, husband and wife, hereby demand judgment against defendants, Baxter, Healthcare and BD, in an amount in excess of one hundred thousand dollars (\$100,000.00), exclusive of interest and costs, together with prejudgment interest, post-judgment interest, delay damages.

**COUNT IV: BREACH OF EXPRESS AND IMPLIED
WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE**

52. Plaintiffs incorporate by reference the averments in all preceding paragraphs of the Complaint as though set forth at length herein.

53. Defendants, Baxter, Healthcare and BD, are the designers, manufacturers, distributors, and sellers of the saline solution, and/or the needle and/or the syringe which were ultimately used by plaintiff's physician, on plaintiff.

54. Defendants, Baxter, Healthcare and BD, sold and delivered their products to Dr. Noone.

55. In selling their products to Dr. Noone, defendants, through their agents, servants, and employees, made representations and promotions concerning the particular purpose to which Dr. Noone would put the products, and knew or should have known of the particular purpose to which Dr. Noone would use the products on the plaintiff.

56. Defendants expressly and impliedly warranted that the saline solution, and/or the needle and/or the syringe were fit for a particular purpose and were safe to use.

57. The products, sold, delivered and shipped by said defendants was defective and harmful and not fit for their particular purpose, and defendants thus breached their implied and express warranty of fitness for a particular purpose.

58. As a direct and proximate result of said defendants' breach of their express and implied warranty of fitness for a particular purpose, plaintiff suffered and continues to suffer from the injuries and losses described herein.

WHEREFORE, plaintiffs, Judith Pusey and Donald Pusey, husband and wife, hereby demand judgment against defendants, Baxter, Healthcare and BD, in an amount in excess of one hundred thousand dollars (\$100,000.00), exclusive of interest and costs, together with prejudgment interest, post-judgment interest, delay damages.

COUNT V- LOSS OF CONSORTIUM

59. Plaintiffs incorporate by reference the averments in all preceding paragraphs of the Complaint as though set forth at length herein.

60. Plaintiff, Donald Pusey, at all times material hereto, is and was the husband of plaintiff, Judith Pusey.

61. As a direct and proximate result of the defendants' conduct, plaintiff, Donald Pusey, has and will sustain damages, which include the deprivation of the services, society, companionship, advise, consortium, and comforts of his wife, plaintiff, Judith Pusey, to which he is legally entitled, all to his great detriment and loss.

WHEREFORE, plaintiffs, Judith Pusey and Donald Pusey, husband and wife, hereby demand judgment against defendants, Baxter, Healthcare and BD, in an amount in excess of one hundred thousand dollars (\$100,000.00), exclusive of interest and costs, together with

prejudgment interest, post-judgment interest, delay damages.

COUNT VI-PUNITIVE DAMAGES

62. Plaintiffs incorporate by reference the averments in all preceding paragraphs of the Complaint as though set forth at length herein.

63. At all times material hereto, defendants, knew that their products were subject to contamination.

64. At all times material hereto, defendants failed to take steps to insure that their products would not become contaminated.

65. At all times material hereto defendants knew that the physicians and other users of their products, or those in the position of the plaintiff, would not become aware of the defective and injurious nature of the products, and would, therefore, use the products on others, such as the plaintiff, to her great detriment and loss.

66. At all times material hereto, defendants failed to notify their customers and users of their products, of the deleterious and defective nature of the products.

67. As a result of the defendants' conduct, as set forth herein, the plaintiff, Judith Pusey, sustained an infection that required the removal of her left breast implant.

WHEREFORE, plaintiffs, Judith Pusey and Donald Pusey, husband and wife, hereby demand punitive damages against Defendants, Baxter, Healthcare and BD.

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